

## Food and Drug Administration, HHS

## § 720.3

### § 710.6 Notification of registrant; cosmetic product establishment registration number.

The Commissioner of Food and Drugs will provide the registrant with a validated copy of Form FD-2511 as evidence of registration. This validated copy will be sent only to the location shown for the registering establishment. A permanent registration number will be assigned to each cosmetic product establishment registered in accordance with the regulations in this part.

### § 710.7 Inspection of registrations.

A copy of the Form FD-2511 filed by the registrant will be available for inspection at the Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

[39 FR 10059, Mar. 15, 1974, as amended at 68 FR 15355, Mar. 31, 2003]

### § 710.8 Misbranding by reference to registration or to registration number.

Registration of a cosmetic product establishment or assignment of a registration number does not in any way denote approval of the firm or its products by the Food and Drug Administration. Any representation in labeling or advertising that creates an impression of official approval because of registration or possession of a registration number will be considered misleading.

### § 710.9 Exemptions.

The following classes of persons are not requested to register in accordance with this part 710 because the Commissioner has found that such registration is not justified:

(a) Beauty shops, cosmetologists, retailers, pharmacies, and other persons and organizations that compound cosmetic products at a single location and administer, dispense, or distribute them at retail from that location and who do not otherwise manufacture or package cosmetic products at that location.

(b) Physicians, hospitals, clinics, and public health agencies.

(c) Persons who manufacture, prepare, compound, or process cosmetic products solely for use in research, pilot plant production, teaching, or

chemical analysis, and who do not sell these products.

## PART 720—VOLUNTARY FILING OF COSMETIC PRODUCT INGREDIENT COMPOSITION STATEMENTS

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AUTHORITY: 21 U.S.C. 321, 331, 361, 362, 371, 374.

SOURCE: 39 FR 10060, Mar. 15, 1974, unless otherwise noted.

### § 720.1 Who should file.

Either the manufacturer, packer, or distributor of a cosmetic product is requested to file Form FDA 2512 ("Cosmetic Product Ingredient Statement"), whether or not the cosmetic product enters interstate commerce. This request extends to any foreign manufacturer, packer, or distributor of a cosmetic product exported for sale in any State as defined in section 201(a)(1) of the Federal Food, Drug, and Cosmetic Act. No filing fee is required.

[57 FR 3129, Jan. 28, 1992]

### § 720.2 Times for filing.

Within 180 days after forms are made available to the industry, Form FDA 2512 should be filed for each cosmetic product being commercially distributed as of the effective date of this part. Form FDA 2512 should be filed within 60 days after the beginning of commercial distribution of any product not covered within the 180-day period.

[57 FR 3129, Jan. 28, 1992]

### § 720.3 How and where to file.

Forms FDA 2512 and FDA 2514 ("Discontinuance of Commercial Distribution of Cosmetic Product Formulation") are obtainable on request from

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the Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at any Food and Drug Administration district office. The completed form should be mailed or delivered to: Cosmetic Product Statement, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, according to the instructions provided with the forms.

[57 FR 3129, Jan. 28, 1992, as amended at 68 FR 15355, Mar. 31, 2003]

### § 720.4 Information requested about cosmetic products.

(a) Form FDA-2512 requests information on:

(1) The name and address, including post office ZIP code of the person (manufacturer, packer, or distributor) designated on the label of the product.

(2) The name and address, including post office ZIP code, of the manufacturer or packer of the product if different from the person designated on the label of the product, when the manufacturer or packer submits the information requested under this paragraph.

(3) The brand name or names of the cosmetic product.

(4) The cosmetic product category or categories.

(5) The ingredients in the product.

(b) The person filing Form FDA-2512 should:

(1) Provide the information requested in paragraph (a) of this section.

(2) Have the form signed by an authorized individual.

(3) Provide poison control centers with ingredient information and/or adequate diagnostic and therapeutic procedures to permit rapid evaluation and treatment of accidental ingestion or other accidental use of the cosmetic product.

(4) Provide ingredient information (and, when requested, ingredient samples) to a licensed physician who, in connection with the treatment of a patient, requests assistance in determining whether an ingredient in the cosmetic product is the cause of the problem for which the patient is being treated.

(c) One or more of the following cosmetic product categories should be cited to indicate the product's intended use.

(1) *Baby products*. (i) Baby shampoos.  
(ii) Lotions, oils, powders, and creams.

(iii) Other baby products.

(2) *Bath preparations*. (i) Bath oils, tablets, and salts.

(ii) Bubble baths.

(iii) Bath capsules.

(iv) Other bath preparations.

(3) *Eye makeup preparations*. (i) Eye-brow pencil.

(ii) Eyeliner.

(iii) Eye shadow.

(iv) Eye lotion.

(v) Eye makeup remover.

(vi) Mascara.

(vii) Other eye makeup preparations.

(4) *Fragrance preparations*. (i) Colognes and toilet waters.

(ii) Perfumes.

(iii) Powders (dusting and talcum) (excluding aftershave talc).

(iv) Sachets.

(v) Other fragrance preparations.

(5) *Hair preparations (noncoloring)*. (i) Hair conditioners.

(ii) Hair sprays (aerosol fixatives).

(iii) Hair straighteners.

(iv) Permanent waves.

(v) Rinses (noncoloring).

(vi) Shampoos (noncoloring).

(vii) Tonics, dressings, and other hair grooming aids.

(viii) Wave sets.

(ix) Other hair preparations.

(6) *Hair coloring preparations*. (i) Hair dyes and colors (all types requiring caution statement and patch test).

(ii) Hair tints.

(iii) Hair rinses (coloring).

(iv) Hair shampoos (coloring).

(v) Hair color sprays (aerosol).

(vi) Hair lighteners with color.

(vii) Hair bleaches.

(viii) Other hair coloring preparations.

(7) *Makeup preparations (not eye)*. (i) Blushers (all types).

(ii) Face powders.

(iii) Foundations.

(iv) Leg and body paints.

(v) Lipstick.

(vi) Makeup bases.

(vii) Rouges.

(viii) Makeup fixatives.

(ix) Other makeup preparations.

(8) *Manicuring preparations*. (i) Basecoats and undercoats.

(ii) Cuticle softeners.